ProtectTexas™
Texas Department of Health

GUIDELINES FOR THE TEXAS HIV MEDICATION PROGRAM

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BACKGROUND - The Texas Department of Health (TDH) has received funding to help offset the cost of medications approved by the Food and Drug Administration (FDA) for the treatment of HIV infection. The program is available to eligible indigent persons with HIV infection, and will provide the following:

PRIORITY 1 MEDICATIONS AND CRITERIA

Antiretroviral Options - A maximum of four (4) of the following medications is allowed:

(1) Nucleoside Reverse Transcriptase Inhibitors (RTIs)

Zidovudine (AZT, Retrovir)
Didanosine (DDI, Videx)
Zalcitabine (DDC, Hivid)
Stavudine (D4T, Zerit)
Lamivudine (3TC, Epivir)
Combivir (AZT 300mg/3TC 150mg) **(counts as two (2) medications)**
Abacavir (Ziagen)
Trizivir (AZT 300mg/3TC 150mg/Ziagen 300mg) **(counts as three (3) medications)**
Emtricitabine (Emtriva)
Truvada (Emtriva/Viread) **(counts as two (2) medications)**
Epzicom (3TC 300mg/Ziagen 600mg) **(counts as two (2) medications)**

(2) Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Nevirapine (Viramune)
Delavirdine (Rescriptor)
Efavirenz (Sustiva)

(3) Protease Inhibitors (PIs)

Fortovase softgel (Saquinavir)
Invirase (Saquinavir)
Ritonavir (Norvir)
Indinavir (Crixivan)
Nelfinavir mesylate (Viracept)
Amprenavir (Agenerase)
Lopinavir/Ritonavir (Kaletra)
Atazanavir (Reyataz)
Fosamprenavir (Lexiva)

(4) Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

Tenofovir (Viread)

(5) Entry Inhibitors

Enfuvirtide (Fuzeon) *Limited availability – capped at 50 clients*

Antiretroviral Qualifications - A person must be diagnosed with HIV infection and have a current CD4+ T Lymphocyte count and Plasma RNA Viral Load count reported to the Texas Medication Program prior to receiving medication.

Newborn infants and pregnant women are a program priority.

(6) Sulfamethoxazole-Trimethoprim (SMZ-TMP), Pentamadine (aerosolized), Dapsone or Trimethoprim - Diagnosed HIV infection and a CD4 cell count less than or equal to 200, **or** diagnosed HIV infection and constitutional symptoms such as thrush or unexplained fever greater than 100 degrees Fahrenheit for greater than two weeks; children under the age of 13 with ACTG clinical indicators. Please note: intravenous pentamidine is also available, but will only be approved for persons under age 13.

PRIORITY 2 MEDICATIONS AND CRITERIA

(7) Acyclovir - Diagnosed HIV infection and acute or chronic herpetic infections.

(8) Fluconazole (Diflucan) – Diagnosed HIV infection and cryptococcal meningitis or esophageal candidiasis.

(9) Itraconazole Suspension (Sporanox Susp.) - Diagnosed HIV infection and esophageal candidiasis.

(10) Itraconazole Capsules (Sporanox Caps) - Diagnosed HIV infection and diagnosed histoplasmosis or blastomycosis.

(11) Clarithromycin (Biaxin) - Diagnosed HIV infection and current or previous diagnosis of Mycobacterium Avium Complex (MAC).

(12) Azithromycin (Zithromax) - Diagnosed HIV infection and current or previous MAC diagnosis and failed therapy on, or intolerance to, Clarithromycin.

(13) Ethambutol (Myambutol) - Diagnosed HIV infection and current or previous diagnosis of MAC.

(14) Ganciclovir (Cytovene) - HIV infection and CMV disease, which has resulted in retinitis or infections of other major organs or organ systems.

(15) Valganciclovir (Valcyte) – HIV infection and CMV disease, which has resulted in retinitis or infections of other major organs or organ systems.

(16) Rifabutin (Mycobutin) - Diagnosed HIV infection and a CD4 cell count at or below 100.

PRIORITY 3 MEDICATIONS AND CRITERIA

(17) Megestrol Acetate (Megace) - AIDS diagnosis and cachexia or anorexia with profound, involuntary, acute weight loss greater than or equal to 10% of baseline body weight or chronic weight loss greater than or equal to 20% of baseline body weight.

(**18) Atovaquone (Mepron) -** Diagnosed HIV infection and acute, mild to moderate Pneumocystis carinii Pneumonia (PCP) and intolerance to Sulfamethoxazole-Trimethoprim (SMZ-TMP).

NOTE Due to numerous issues concerning product availability, please contact the THMP directly should you wish to apply for and obtain the following medications:

(19) Interferon-Alpha - Diagnosed HIV infection & diagnosed, disseminated Kaposi's Sarcoma with a CD4 count > 200.

(20) Amphotericin-B - Diagnosed HIV infection and progressive, potentially fatal disseminated fungal infections.

(21) Immune Globulin Intravenous (Human) (IVGG) - Diagnosed HIV infection and younger than 18 years of age.

ELIGIBLE PERSONS - Any Texas resident who:

(1) has a diagnosis of HIV disease and meets the drug-specific eligibility criteria of one or more of the drugs listed above and;

(2) is under the care of a Texas-licensed physician who prescribes the medication(s) and;

(3) meets the financial eligibility criteria of the program.

CRITERIA FOR FINANCIAL ELIGIBILITY - A person is financially eligible if he or she:

(1) is not presently covered for the medication(s) under the Texas Medicaid Program, or has utilized their Medicaid pharmacy benefits for the month and;

(2) is not covered for the medication(s) by any other third-party payor and;

(3) has an adjusted gross income, when combined with the gross income of his/her spouse, that does not exceed 200 percent of the current Federal Poverty Income Guidelines (as shown below). TDH will determine if the person satisfies this criterion from information provided by the person on the Program application.

If the demand for the priority 1 medications increases beyond the budget capacity to continue to furnish all the medications on the formulary, the program will begin to eliminate the medications in priority 3 and then priority 2, as necessary. The program will not abruptly cease purchasing priority 2 and 3 medications. The process will be gradual to allow individuals currently taking priority 2 and 3 medications an opportunity to look for other programs to provide these medications. Providing medications according to their priority will serve as the budgetary control to purchase all medications on the formulary.

INCOME GUIDELINES

If the size of the family unit is:	The family gross annual income may not exceed:
1	$18,620
2	$24,980
3	$31,340
4	$37,700
5	$44,060
>5	$ 6,360 each additional person

OBTAINING THE APPLICATION MATERIALS - An application packet containing instructions & all necessary forms, may be requested by telephoning toll-free 1-800-255-1090, downloading forms from **www.tdh.state.tx.us/hivstd/meds** , or writing to:

Texas Department of Health
Texas HIV Medication Program
1100 West 49th Street
Austin, Texas 78756

ATTN: MSJA

DEFINITION OF FAMILY AND HOUSEHOLD FOR DETERMINING FAMILY SIZE/INCOME - Family members whose incomes are considered are the applicant and his or her spouse (or common-law spouse), if applicable. For minor children, the child's parents' income is considered. (These persons must be living in the same household.) For determining household size, the applicant, spouse, and their dependent children shall be included. A dependent child is a child under the age of 18 who is the biological, adoptive, or stepchild of the applicant. A child applicant is a person under the age of 18, living with his or her parent(s).

FOSTER CHILDREN - In cases where a welfare agency is legally responsible for the child and the foster home is, in fact, an extension of the welfare agency, the foster child is considered a one-member family. Therefore, if the foster child's income is not above the income guidelines, the foster child meets the income criteria.

DOCUMENTATION OF FINANCIAL ELIGIBILITY - The applicant must document his or her income on the application form, and provide verification of income with check stubs, W-2 forms, copies of benefit entitlement letters. If zero income is reported, the income verification form must be completed along with a letter of explanation signed by the applicant explaining when and where he/she was last employed and how he/she is able to live on zero income/cash assistance.

DOCUMENTATION OF MEDICAL ELIGIBILITY - All applications for new clients must be mailed in to the program. Medical Certification Forms must be submitted for all medication changes. The medical certification forms should only be faxed for clients in immediate need of changes to be made to their approved formulary so as not to disrupt their progress on combination antiretroviral therapy.

DETERMINING INITIAL FINANCIAL ELIGIBILITY - Using the current Public Health Service discount prices, TDH will calculate the annual cost of Program formulary medications that the applicant=s physician has qualified them for, and subtract that amount from his/her gross annual income. If the applicant's adjusted gross income at the time of application is below the guidelines, he/she is financially eligible. If income is above the guidelines, he/she is financially ineligible. The applicant should be encouraged to request reconsideration if his/her income status changes such that it is within the Program parameters.

CONFIDENTIALITY - TDH regards the information in the application as part of the applicant's medical record and confidential by law. No information that could identify the individual applicant will be released except as authorized by law. Within TDH, physical security and administrative controls exist to safeguard the confidentiality of the applications and other means of identifying the individual. Applicants should realize that, in addition to TDH, their physician and pharmacist will be aware of the diagnosis.

PROVISION OF MEDICATION(S) - The Program will provide the following medication(s) each month:

PRIORITY 1 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES

(1) A maximum of 400 capsules of 100 mg zidovudine (AZT, Retrovir) - #100/btl, or
A maximum of 60 tablets of 300 mg zidovudine (AZT, Retrovir) - #60/btl;
- Zidovudine suspension is available in 10 mg/ml, 240 ml (8 oz) bottles, 8 bottles maximum.
- IV zidovudine is available in 10 mg/ml, 2 ml vials, 20 vials maximum.

(2) A maximum of 120 chewable tablets of didanosine (DDI, Videx) - #60/btl, or
A maximum of 60 chewable tablets of 200 mg didanosine (DDI,Videx) - #60/btl, or
A maximum of 30 enteric coated capsules of didanosine EC (Videx EC) - #30/btl;
- Strengths available are 25 mg, 50 mg, 100 mg, 150 mg or 200 mg chewable tablets; 125 mg, 200 mg, 250 mg, or 400 mg enteric coated capsules; or 2 gm or 4 gm pediatric powder (4 units max for pediatric powder).

(3) A maximum of 100 tablets of zalcitabine (DDC, Hivid) - #100/btl;
- Strengths available are 0.375 mg, or 0.750 mg tablets.

(4) A maximum of 60 capsules of stavudine (D4T, Zerit) - #60/btl;
- Strengths available are 15 mg, 20 mg, 30 mg or 40 mg capsules.
- Stavudine suspension is available in 1 mg/ml, 200 ml (6.67 oz) bottles, 12 bottles maximum.

(5) A maximum of 60 capsules of 150 mg lamivudine (3TC, Epivir) - #60/btl, or
A maximum of 30 tablets of 300 mg lamivudine (3TC, Epivir) - #30/btl;
- Lamivudine suspension is available in 10 mg/ml, 240 ml (8 oz) bottles, 4 bottles maximum.

(6) A maximum of 60 tablets of Combivir (AZT 300 mg/3TC 150 mg) - #60/btl;

(7) A maximum of 60 tablets of 300 mg abacavir (Ziagen) - #60/btl;
- Abacavir suspension is available in 20 mg/ml, 240 ml (8 oz) bottles, 4 bottles maximum.

(8) A maximum of 60 tablets of Trizivir (AZT 300mg/3TC 150mg/Ziagen 300mg) - #60/btl;

(9) A maximum of 30 capsules of 200 mg emtricitabine (Emtriva) - #30/btl;

(10) A maximum of 30 tablets of Truvada (Viread 300 mg/Emtriva 200 mg) - #30/btl;

(11) A maximum of 30 tablets of Epzicom (Epivir 300 mg/Ziagen 600 mg) - #30/btl;

(12) A maximum of 540 capsules of 200 mg saquinavir softgel (Fortovase softgel) - #180/btl;

(11) A maximum of 270 tablets of 200 mg invirase (Saquinavir) - #270/btl;

(12) A maximum of 360 gelcaps of 100 mg ritonavir (Norvir) - #120/btl;
- Ritonavir suspension is available in 80 mg/ml, 240 ml (8 oz) bottles, 2 bottles maximum.

(13) A maximum of 360 capsules of 200 mg indinavir (Crixivan) - #360/btl, or
A maximum of 270 capsules of 333 mg indinavir (Crixivan) - #135/btl, or
A maximum of 180 capsules of 400 mg indinavir (Crixivan) - #180/btl;

(14) A maximum of 300 tablets of 250 mg nelfinavir mesylate (Viracept) - #300/btl, or
A maximum of 120 tablets of 625 mg nelfinavir mesylate (Viracept) – #120/btl;
- Nelfinavir oral powder is available in 50 mg/gm, 144 gm bottles for pediatric use, 12 bottles maximum.

PRIORITY 1 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES (Continued)

(15) A maximum of 480 capsules of 150 mg amprenavir (Agenerase) - #240/btl, or
A maximum of 720 capsules of 150 mg amprenavir **if used with Sustiva** - #240/btl, or
A maximum of 960 capsules of 50 mg amprenavir (Agenerase) - #480/btl;
- Amprenavir suspension is available in 15 mg/ml, 240 ml (8 oz) btls, 10 btls max pediatric/24 btls max adult.

(16) A maximum of 180 gelcaps of 133.3 mg/33.3 mg lopinavir/ritonavir (Kaletra) - #180/btl;
- Kaletra suspension is available in 400 mg/100 mg/5 ml, 160 ml bottles for pediatric use, 2 btls max.

(17) A maximum of 60 capsules of atazanavir (Reyataz) - #60/btl;
- Strengths available are 100 mg, 150 mg, or 200 mg capsules.

(18) A maximum of 60 tablets of fosamprenavir (Lexiva) - #60/btl, taken in the recommended boosted dose (one bottle per month, taken with low-dose ritonavir as an additional antiretroviral). Consultation with the THMP Physician is required for unboosted doses (two bottles per month, taken without low-dose ritonavir).

(19) A maximum of 60 tablets of 200 mg nevirapine (Viramune) - #60/btl;
- Nevirapine suspension is available in 50 mg/5 ml, 240 ml/bottles, 12 bottles maximum.

(20) A maximum of 180 capsules of 200 mg delavirdine (Rescriptor) - #180/btl;

(21) A maximum of 30 tablets of 600 mg efavirenz (Sustiva) - #30/btl, or
A maximum of 90 capsules of 200 mg efavirenz (Sustiva) - #90/btl, or
A maximum of 90 capsules of 100 mg efavirenz (Sustiva) - #30/btl, or
A maximum of 90 capsules of 50 mg efavirenz (Sustiva) - #30/btl;

(22) A maximum of 30 tablets of 300 mg tenofovir (Viread) - #30/btl;

(23) A maximum of 1 injection kit of 90 mg enfuvirtide (Fuzeon) - #60 vials/kit;

(24) A maximum of 200 tablets of 800 mg/160 mg SMZ-TMP DS - #100/btl;
- SMZ-TMP suspension is available in 200 mg/40 mg/5 ml, 473 ml (1 pint) bottles, 2 bottles maximum.

(25) A maximum of 100 tablets of dapsone - #100/btl;
- Strengths available are 25 mg or 100 mg tablets.

(26) A maximum of 1 vial of 300 mg aerosolized pentamidine (Nebupent) - #1 vial, or
A maximum of 10 vials of 300 mg IV pentamidine (Nebupent)
- TDH will provide a supply of either SMZ-TMP DS, dapsone, or pentamidine each month.

(27) A maximum of 100 tablets of 200 mg trimethoprim - #100/btl;

PRIORITY 2 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES

(28) A maximum of 200 capsules/tablets of acyclovir - #100/btl;
- Strengths available are 200 mg capsules, 400 mg or 800 mg tablets.

(29) A maximum of 60 tablets of fluconazole (Diflucan) - #30/btl;
- Strengths available are 50 mg, 100 mg or 200 mg tablets.

(30) A maximum of 120 capsules of 100 mg itraconazole (Sporanox) - #30/btl;
- Itraconazole suspension is available in 10 mg/ml, 150 ml (5 oz) bottles, 2 bottles maximum.

(31) A maximum of 60 tablets of 500 mg clarithromycin (Biaxin) - #60/btl;

(32) A maximum of 60 tablets of 250 mg azithromycin (Zithromax) - #30/btl, or
A maximum of 30 tablets of 600 mg azithromycin (Zithromax) - #30/btl;
- TDH provides either clarithromycin or azithromycin each month.

(33) A maximum of 100 tablets of 400 mg ethambutol (Myambutol) - #100/btl;

(34) A maximum of 100 capsules of 150 mg rifabutin (Mycobutin) per 7-week period - #100/btl;

(35) A maximum of 360 capsules of 250 mg ganciclovir (Cytovene) - #180/btl, or
A maximum of 180 capsules of 500 mg ganciclovir (Cytovene) - #180/btl, or
A maximum of 50 vials of 500 mg IV ganciclovir (IV Cytovene);

PRIORITY 2 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES (Continued)

(36) A maximum of 120 tablets of 450 mg valganciclovir (Valcyte) during the first month of treatment, with a maximum of 60 tablets each month thereafter - #60/btl;
- TDH provides either ganciclovir or valganciclovir each month.

PRIORITY 3 MEDICATION STRENGTHS AND MAXIMUM QUANTITIES

(37) A maximum of 3 bottles of 40 mg/ml megestrol acetate suspension (Megace) - 240ml btl;

(38) A maximum of 2 bottles of 750 mg/5 ml atovaquone suspension (Mepron) per 21-day treatment therapy, following **each** diagnosis of PCP - 210 ml btl;

(39) A maximum of 50 vials of 18 mu interferon-alpha;

(40) A maximum of 50 vials of 50 mg amphotericin-B;

(41) A maximum of 4 vials of IVIG for pediatric usage;
- Strengths available are 2.5 mg and 5 mg vials.

Due to numerous issues concerning product availability, please contact the THMP directly should you wish to apply for and obtain the following medications: interferon-alpha, amphotericin-B, or IVIG.

***** PLEASE NOTE: ALL MEDICATIONS MUST BE DISPENSED IN FULL BOTTLE AMOUNTS. *****

PAYMENT OF A FEE BY THE PATIENT - Persons who have been approved by TDH for Program financial assistance and are not Medicaid eligible may be required to pay a $5.00 co-payment fee per prescription to the participating pharmacy for each month's supply at the time the drug is dispensed.

MEDICAID ELIGIBLE APPLICANTS - Applicants who are eligible for Medicaid assistance benefits must first utilize their Medicaid pharmacy benefits in order to be eligible to receive medications from the Program. Medicaid eligible applicants will be assigned to the nearest available pharmacy outlet to receive medication. The pharmacy will not charge the $5.00 co-payment to the patient.

PARTICIPATING PHARMACY - TDH has designated specific pharmacies throughout the state to dispense medications for approved Program clients. In order to ensure optimal physical security of the drugs and administrative control of the program, persons approved for the Program must obtain their medications from the pharmacy to which they are assigned. Clients may call the Program anytime at 1-800-255-1090 or (512) 490-2510 to request assignment to a different participating pharmacy. Should the choices available for pharmacy assignments prove a hardship to the patient, they must explain to TDH in writing why a hardship exists. The applicant must include in the explanation the name, address, and person to contact at the pharmacy where they would like to receive their medication(s). If that pharmacy wishes to participate in the program, TDH will supply that pharmacy with a Program pharmacy agreement to complete and return to the Department.

PROCEDURE FOR RECEIVING MEDICATION - An approved Program patient will receive the written prescription(s) from his or her physician for medication covered by the Program, and present it to their assigned pharmacy. The physician may also phone or fax prescription(s) to the pharmacy each month on the patient's behalf. The pharmacy will order the medication from the Program using the assigned patient code and dispense to the patient upon receipt of the medication from the pharmaceutical supplier(s).